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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,787	08/16/1999	THOMAS EMRICH	BMID9913US	2784

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EXAMINER	
ZEMAN, ROBERT	
ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/284,787	Applicant(s) EMRICH ET AL.	
	Examin r Robert A Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on 2-4-2002 is acknowledged. Claims 10-19 have been canceled. Claims 18-25 have been added and are currently under examination.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, there are sequences listed in the Specification without the requisite SEQ ID NOs.(see pages 2-5 and 7).

The use of the trademark BIAcore (see page 9 for example) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that mouse myeloma cell line P3x63-Ag8.653 is required in order to practice the invention as claimed (claims 20-21 and 23-25). The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention {see 37 CFR 1.808(a)}. Alternatively Applicant may be able to demonstrate that the mouse myeloma cell line is well known and readily available to the public.

Additionally, with regard to claim 22 it is apparent that the hybridoma R 3A12 is required in order to practice the claimed invention. The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention {see 37 CFR 1.808(a)}. The Examiner acknowledges the deposit of organisms under Deutsche Sammlung fur Mikroorganismen und Zelkuturen under Accession No. DSM ACC2286 (08.10.1996) in partial compliance with this requirement. However, the deposits are not in full compliance with 37 CFR 1.803-1.809.

If a deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by the depositor on the availability to the public of the deposited material will be

irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, should be submitted stating that the deposit has been made at an acceptable depository *and that* the following criteria have been met:

1) During the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

2) All restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

3) The deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

4) A viability statement in accordance with the provisions of 37 CFR 1.807; and

5) The deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 19 are rendered vague and indefinite by the use of the phrase "An antibody comprising a monoclonal antibody". Said language is confusing. A given antibody is either monoclonal or polyclonal by nature. It is suggested that the phrase "A monoclonal antibody" be used instead.

Claims 18 and 19 are rendered vague and indefinite by the use of the phrase "having an affinity of "X" against the epitope..." Said term is contradictory. An antibody has an affinity for the antigen/ligand to which it binds.

Claim 22 is rendered vague and indefinite by the use of the term "under the No.". It is unclear whether Applicant is referring to an Accession Number or some other type of number.

Claim 23 is rendered vague and indefinite by the use of the term "with a high affinity" in the recitation of step (e). Said term is confusing. A high affinity to what? Also, As written, it is impossible to determine the metes and bounds of the claimed invention.

The term "high" in claim 23 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hinds et al. (Journal of Medicinal Chemistry, 1991 Vol. 34, No. 6, pages 1777-1789 – IDS-6).

The instant claims are drawn to monoclonal antibodies with a binding specificity for the sequence YPYDVPDYA. Hinds et al. disclose antibodies with a binding specificity to the sequence YPYDVPDYA (see abstract). Hinds et al. is silent regarding the specificity of said antibodies. However, it would be obvious to one of skill in the art to select those antibodies with the highest affinities.

Claim Rejections - 35 USC § 103

Claims 18-21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hinds et al. (Journal of Medicinal Chemistry, 1991 Vol. 34, No. 6, pages 1777-1789 – IDS-6) in view of Kuby (Immunology, Second Edition, W.H. Freeman and Company, 1994, pages 160-164)

The instant invention is drawn to monoclonal antibodies with a binding specificity for the sequence YPYDVPDYA and methods of making said monoclonal antibodies utilizing peptides comprising the sequence YPYDVPDYA (and derivatives thereof), rodents and a murine myeloma cell line.

Hinds et al. disclose antibodies with a binding specificity to the sequence YPYDVPDYA (see abstract). Hinds et al. do not disclose the exact method steps recited in the instant claims. Specifically, Hinds et al. does not explicitly disclose the use of the P3-x63-AF8.653 murine myeloma cell line or the use of Lou/C rats. However, as disclosed by Kuby, the methodology for producing monoclonal antibodies is well known in the art. An animal (rodent) is challenged with the antigen of interest. Spleen cells (source of primed B cells) are harvested from said animal and fused with $HGPRT^-$; Ig^- immortalized myeloma cells in polyethylene glycol. The resulting hybridomas are selected using HAT containing medium and screened for antibody production. Hybridomas producing the desired antibody are then subcloned. Since the production a given monoclonal antibody is predicated on the antigen used to immunize the animal, the selection of a specific animal and/or myeloma cell line merely constitutes a conventional alternative to the method disclosed by Kuby and hence would have been obvious to one of skill in the art.

Conclusion

No claim is allowed.

Claim 22 is free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
April 18, 2002